## §318.23

## § 318.23 Heat-processing and stabilization requirements for uncured meat patties.

- (a) *Definitions*. For purposes of this section, the following definitions shall apply:
- (1) Patty. A shaped and formed, comminuted, flattened cake of meat food product.
- (2) Comminuted. A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.
- (3) Partially-cooked patties. Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.
- (4) Char-marked patties. Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.
- (b) Heat-processing procedures for fully-cooked patties. (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

PERMITTED HEAT-PROCESSING TEMPERATURE/
TIME COMBINATIONS FOR FULLY-COOKED
PATTIFS

Minimum internal temperature at the center of each patty (Degrees)		Minimum holding time after required internal temperature is reached
Fahrenheit Or centigrade	(Time)	
	Minutes	Or seconds
66.1	.68	41
66.7	.54	32
67.2	.43	26
67.8	.34	20
68.3	.27	16
68.9	.22	13
69.4 (and up)	.17	10
	or centigrade  66.1	Ach patty rees) time after internal ter is rea (Tin Minutes)  66.1

(2) The official establishment shall measure the holding time and temperature of at least one fully-cooked patty from each production line each hour of production to assure control of the heat process. The temperature meas-

Contributing Ingredients, 1.0=Percent Allowance for Group 2 Protein-Contributing Ingredients, 4=Moisture-Protein Ratio for Cooked Sausage.

uring device shall be accurate within 1 degree F.

- (3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.
- (ii) In addition, in the case of a heating deviation, the official establishment may reprocess the affected product, using one of the methods in paragraph (b)(1) in this section; use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (b)(1) in this section, provided this does not violate the final product's standard of composition, upset the order of predominance of ingredients, or perceptibly affect the normal product characteristics; or relabel the affected product as a partiallycooked patty product, if it meets the stabilization requirements in paragraph (c) of this section.
- (c) Stabilization. (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than a 1 log 10 multiplication of Clostridium perfringens, within the product.
- (2) For each meat patty product produced using a stabilization process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in \$301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

- (3) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.
- (4) Partially cooked patties must bear the labeling statement "Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F.)." The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (5) Char-marked patties must bear the labeling statement "Uncooked, Char-marked: For Safety, Cook Until Well Done (Internal Meat Temperature 160 degrees F.)." The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

[64 FR 744, Jan. 6, 1999]

## § 318.24 Compliance procedures for meat derived from advanced meat/ bone separation machinery and recovery systems.

- (a) The product resulting from the separating process shall not have a calcium content exceeding 0.15 percent or 150 mg/100 gm of product within a tolerance of 0.03 percent or 30 mg, as prescribed in §301.2(rr)(2) of this subchapter.
- (b) To verify the calcium content in meat derived from advanced meat/bone separation machinery and recovery systems, a compliance program consisting of the following parameters shall be followed by manufacturers of meat defined in §301.2(rr)(2) of this subchapter.
- (1) An analysis of a sample of at least 1 pound from each lot shall be performed by the operator of the estab-

lishment or his or her agent. For purposes of this paragraph, a lot shall consist of the meat derived from advanced meat/bone separation machinery and recovery systems, designated as such by the operator of the establishment or his or her agent, from the product produced from a single species of livestock in no more than one continuous shift of up to 12 hours. Individual results from the chemical analyses shall be compared to the calcium limit, prescribed in paragraph (a) of this section, in order to demonstrate compliance. If compliance is not demonstrated, that is, if any single analytical result is more than 0.18 percent, 12 before product from a production lot that is still at the establishment or one that is subsequently produced can be considered to be in compliance, at least three samples from that production lot shall be taken and analyzed for calcium, either separately, or, at the option of the establishment, as a composite (i.e., combining the three samples for analysis). The average of the results or the composite result must be less than or equal to 0.15 percent. Taking three samples from each subsequently produced lot and analyzing them in order to demonstrate compliance shall continue until five consecutive lots have mean or composite results less than or equal to 0.15 percent. If the statistical evidence indicates that a production lot is not in compliance with the calcium limit, as prescribed in §301.2(rr)(2) of this subchapter, the lot must be labeled as MS(S) and meet all of the requirements for MS(S) in §319.5 of this subchapter.

(2) The management of the establishment must maintain records to support the validity of the calcium content (as a measure of bone solids) to assure the

<sup>&</sup>lt;sup>1</sup>The value 0.18 percent was derived by multiplying by 3 the expected analytical standard deviation obtained by FSIS laboratories on the approved chemical procedure for measuring calcium which uses Ethylenediaminetetraacetic acid (EDTA) as provided in the "Official Methods of Analysis of the AOAC International" (formerly the Association of Official Analytical Chemists), 15th Ed. (1990).

<sup>&</sup>lt;sup>2</sup>Individual or an average of results shall be rounded to the nearest 0.01 percent calcium